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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/511,481	02/23/2000	Gary J. Becker	97-998 US - DIV.	3875

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 12/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary

Application No.

09/511,481

Applicant(s)

BECKER, GARY J.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62-70 is/are allowed.
- 6) ☒ Claim(s) 21-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/094,402.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species I of Figures 1, 2 and 4 and the subspecies 3A, claims 21-70 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the election of species and subspecies on the basis of the number and shape of the connection elements is improper and contrary to the disclosure of the specification. This is found persuasive.

2. Applicant is reminded that this traversal on the grounds that the species are not patentably distinct, and this submission of evidence or identification of such evidence now of record shows the species to be obvious variants or clearly admits on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "first diameter d" mentioned on page 12, line 21 is not in Figure 1 or any of the other figures. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because reference number "1" in Figure 5 does not have a lead line. A proposed drawing correction or corrected drawings are required in reply to the

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Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 37-39, 42, 45, 55 and 62 are objected to because of the following informalities:

- ✓ a. Claim 37, line 2, "ends" should be changed to --two end sections--.
- ✓ b. Claim 37, line 3, "filaments" should be changed to --filament--.
- ✓ c. Claim 37, line 3, "prorogating" should be changed to --propagating--.
- ✓ d. Claim 38, both lines 1 and 2, --section-- should be inserted after "end".
- ✓ e. Claim 39, line 2, --section-- should be inserted after each "end".
- ✓ f. Claim 42, line 1, the "a" should be deleted.
- ✓ g. Claim 42, line 3, "L_{hel}1" should be changed to --L_{hel}1--.
- ✓ h. Claim 45, line 1, "sections" should be changed to --section--.
- ✓ i. Claim 45, line 2, --length-- should be inserted after "having a".
- ✓ j. Claim 55, line 26, --imaginary-- should be inserted after "second".
- ✓ k. Claim 62, line 18, --element-- should be inserted after "expandable".

Appropriate correction is required. It is applicant's responsibility to review each claim and make any other necessary corrections.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 21-34, 36 and 40-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 21, 44 and 46 claim a stent having square edges. While the specification on page 10, lines 8-21 does state that the endoprosthesis has a square-like tubular end, there is no support for the endoprosthesis having square edges. Claim 24 claims that first and second segments cross each other. This is new matter because there is no support in the specification or drawings. Claims 29, 36 and 41 all claim that the circumferential dimension of the segment(s) varies. None of the Figures show a variation in the circumferential dimension along the helical length, so it is therefore new matter.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-34, 36 and 40-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 21, 44 and 46 are indefinite because it is unclear what is being determined as an edge. Are the ends of the stent an edge, or can any filament have an edge?

10. Claims 28-30, 36, 40 and 41 are indefinite because it is not clear how the circumferential dimension is being measured. How is it parallel to the circumference of the stent and varying along its helical length? Is the stent in an expanded or crimped configuration when the

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circumferential dimension is varying? Examiner requests that applicant point out in the specification how the circumferential dimension is being defined as well as how it varies by way of the figures.

✓ 11. Claim 47 recites the limitation "the longitudinal axis" in line 4. There is insufficient antecedent basis for this limitation in the claim.

12. It is applicant's responsibility to review each claim and make any other necessary corrections.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. Claims 21-23, 26-46 and 55-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogi et al. (USPN 5,925,061).

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Ogi et al. discloses a stent with all the elements of claims 21, 35, 37 and 55. See Figure 7 for first and second square edges at the ends of the stent. The bottom two rows of peaks and valleys are being designated the first segment and the above two rows are being designated the second segment. Both propagate helically with respect to the longitudinal axis of the main body and are joined together by integral (column 2, lines 32-44) connecting elements (18).

Claims 22 and 35, see Figure 7 for designated first segment and second segment having pitches that are different.

Claim 23, see Figure 7 for first and second segments being generally parallel.

Claims 26-27, see column 6, lines 8-19 for self-expanding and plastically deformable materials.

Claims 28-30, see Figure 7.

Claims 31-32 are product-by-process claims, and according to MPEP § 2113, these claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. See column 5, lines 45-60.

Claim 33, see Figure 7 for bottom row of first segment having varying amplitude.

Claim 34, see Figure 7 for pattern being generally sinusoidal.

Claim 36, see Figure 7.

Claim 37, see Figure 7 for second pitch of second pattern of designated second segment being less than the first pitch of the first pattern of the designated first segment.

Claims 38-42, see Figure 7.

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Claim 43, see Figure 7 for first pattern of designated first segment having changing amplitude.

Claims 44 and 46, see rejections to claim 21 *supra*.

Claim 45, see Figure 7.

Claim 55, see Figure 7 for connecting elements forming first imaginary helical line substantially parallel to a second imaginary helical line.

Claims 56-61, see Figure 7.

15. Claims 47-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Moriuchi (USPN 6,013,854).

Moriuchi discloses a stent with all the elements of claim 47. See Figures 5 and 6 for a plurality of filament segments arranged to form a first repetitious pattern comprised of peaks and valleys and that advances substantially helically along the longitudinal axis. Figure 6 clearly shows a plurality of connecting segments connecting peaks to valleys. See columns 3-4, lines 62-10 for the connecting segments and the peaks and valleys they connect being comprised of a continuous piece of material.

Claims 48-53, see Figure 6.

Claim 54 is a product-by-process claim, and according to MPEP § 2113, this claim is not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. See columns 3-4, lines 62-10.

Allowable Subject Matter

16. Claims 62-70 are allowed.
17. Claims 24 and 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

18. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

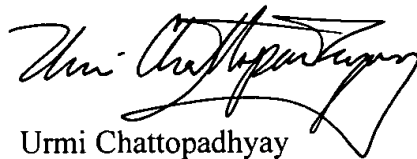
19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

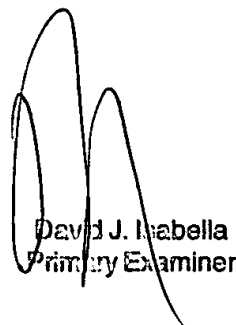


Urmi Chattopadhyay

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December 4, 2002



David J. Hebella
Primary Examiner